

## Corresponding Responsibility of the Pharmacist

### Objectives

By completing the lesson, the pharmacist will be able to:

1. Identify the legal standard for dispensing medications pursuant to a valid prescription.
2. Discuss the legitimate medical purpose standard.
3. List factors the pharmacist should consider in considering whether to dispense medication for a legitimate medical purpose.
4. Discuss legal literature directed to the legitimate medical purpose standard.

### Introduction

Depending on the practice setting, a pharmacist may dispense dozens of prescriptions per month, or week, or even per day. For each of those prescriptions, the pharmacist has a duty to ensure the prescription is valid. To be valid, the prescription must be issued for a legitimate medical purpose by an individual prescriber acting in the usual course of his/her professional practice – typically a physician, physician assistant, nurse practitioner, veterinarian, or dentist.

While the responsibility for the proper prescribing is upon the prescriber, a corresponding responsibility rests with the pharmacist who dispenses the prescription. In other words, the pharmacist can not fulfill all legal duties by merely accurately selecting the proper pharmaceutical product and accurately labeling that product for use by the patient and counseling the patient. This lesson will describe parameters to determine when and whether the pharmacist is discharging the corresponding responsibility to determine whether any given prescription is valid or invalid.

### **Rule 4729-5-21 and Rule 4729-5-30**

(A) A prescription, to be valid, must be issued for a **legitimate medical purpose** by an individual prescriber acting in the usual course of his/her professional practice. The responsibility for the proper prescribing is upon the prescriber, but a **corresponding responsibility rests with the pharmacist who dispenses the prescription**. An order purporting to be a prescription issued not in the usual course of bona fide treatment of a patient is not a prescription and the person knowingly dispensing such a purported prescription, as well as the person issuing it, shall be subject to the penalties of law.

One thing to notice about this rule is that there are no numerical safe harbors. In other words, no pharmacist can always be safe so long as no more than one hundred units [or any other number] per month of a given medication is dispensed.

David Brushwood has popularized a “VIGIL” approach to be used in prescribing or dispensing controlled substances for a legitimate medical purpose. VIGIL stands for:

- Verification – of legitimacy of prescribing and dispensing controlled substances for a given patient

- Identification – use of government issued ID by patient and family members picking up prescriptions.
- Generalization – rules for handling controlled substances, (e.g. keep prescription drugs locked up, no sharing, have scripts filled during hours when your prescriber can be contacted if necessary)
- Interpretation – deciding whether to dispense or prescribe free from bias and prejudice, objectively assessing each dispensing decision.
- Legalization – keeping up with legal requirements, making sure proper dispensing documentation is maintained.

Another thing to notice is that the statute is not limited to products containing hydrocodone (e.g. Vicodin, Lortab, Norco) or oxycodone (e.g. Percocet, Oxycontin). Because of the addictive nature of these medications, they are perhaps more prone to be abused, and thus not prescribed or dispensed for a legitimate medical purpose. It is also possible that an anabolic steroid (e.g. Anadrol, testosterone) or any other type of prescription drug is not being prescribed and dispensed for a legitimate medical purpose.

The next thing to notice is that not properly assessing the situation can subject the pharmacists to penalties of law. These penalties include criminal prosecution (e.g. fines, incarceration, and probation) and administrative measures by the Ohio Board of Pharmacy (e.g. fines, suspension, and practice restriction). Criminal liability requires proof that the accused engaged in a voluntary act or omission prohibited by law with the requisite degree of culpability for each element of the offense the law specifies. R.C. 2901.21(A). In other words, there needs to be a “guilty state of mind.”

To be subject to penalties of law, the pharmacist must act knowing. The term “knowingly” with regard to information means that a person has actual knowledge of the information, or acts in deliberate or reckless disregard of the truth or falsity of the information. Thus, there are two ways for a pharmacist to knowingly fill a prescription for an illegitimate purpose. The pharmacist may actually know a prescription is illegitimate (such as when a pharmacist writes a fake prescription then fills it). The pharmacist may also recklessly disregard whether the prescription is for a legitimate medical purpose. This lesson is primarily directed to the “reckless disregard” types of dispensing instances and how to avoid them. This lesson is primarily directed to the dispensing of controlled substances used to treat pain.

As health care professionals, pharmacists have been taught to, and rightfully want to, provide needed controlled substances for their patients. Untreated pain and under-treated pain are real and serious problems. The American Academy of Pain Medicine estimates that 50 million people suffer from chronic pain each year, and an additional 25 million suffer from acute pain arising from injuries or surgery. Pain is often under-treated. Although effective treatments are available, pain management is adequate only 25% of the time.

Poor pain management can produce a number of negative effects, such as impaired immune responses and impaired movement with increased risk of thromboembolism, and

can actually contribute to the development of a chronic pain state. Unrelieved suffering can produce anxiety, depression, hostility, and sleep deprivation. A recent pain survey of 1,500 adults in Michigan found that approximately twenty percent of adults suffer from chronic pain and that seventy percent of patients had continued pain even with treatment, with nearly half feeling depressed about their pain. While additional statistics can be quoted on point, most pharmacists with day to day encounters with patients face real life examples of pain which are difficult to treat.

Pharmacists and patients face a number of challenges with prescribers and patients - who may feel frustrated because there is no “cure” for the underlying cause of the pain. Musculoskeletal damage and other ailments may not have a once-and-for-all complete fix – even with skillful surgery. While cancer patients often have a diagnosis that is associated with “legitimate” pain, patients with lower back pain and other long term neuralgias that don’t have such a clear cut diagnosis can prove very frustrating to diagnose and treat. To compound the problem, there really are dishonest people who attempt to fake injury and pain in order to obtain medications that can be resold illegally.

Patients themselves can also be a source of problems. They may feel reluctant to discuss pain with their pharmacist and medical providers. They may feel concerned about being labeled as a drug abuser and may be fearful of becoming addicted when taking prescribed narcotics. They may also forget, minimize or exaggerate symptoms, whether unintentionally or otherwise.

Fortunately, such problems have not gone unnoticed. While a detailed discussion of the state of the art in treating pain is beyond the scope of this lesson, the reader may want to review standards articulated at:

- Joint American Academy of Pain Medicine/American Pain Society consensus statement on the use of opioids for the treatment of chronic pain (the AAPM/APS guidelines) at <http://www.ampainsoc.org/advocacy/opioids.htm>
- Model Guidelines for the Use of Controlled Substances for the Treatment of Pain (the “Model Guidelines”), which was developed by the Federation of State Medical Boards of the United States and can be viewed at <http://www.medsch.wisc.edu/painpolicy/domestic/model.htm>
- <http://www.painmed.org> (American Academy of Pain Medicine)
- <http://www.ampainsoc.org> (The American Pain Society)

A number of possible risk factors prescriptions for a non-legitimate medical purpose include:

- Younger patients
- Large cash payments
- Scripts written for large quantities
- Doctors located far away
- Scripts presented to pharmacy late at night or weekends
- Missing information on script – e.g. DEA number
- Patient appears to be nervous or in a hurry
- Early refills without a change in directions or other good reason

- Patient has scripts for multiple medications but only wants the controlled substances
- Something “just don’t look right” – J.D.L.R.
- Scripts from emergency room for a large supply. For example, a ninety day supply of medication would typically not come from an emergency room.

No matter whom you work for or whom you work with, you do NOT have to fill every prescription that comes across the counter. While it is true that nobody wants to turn away business or disappoint a patient (or an employer), the pharmacist must use professional judgment.

### **Why the Law is Vague**

In short, the law is somewhat vague because of the difficulty in writing a law that is both very clear, and covers all possible situations of prescribing and dispensing medications. Actually, proponents of the law would say that the law is not vague – it is just a “flexible” legal standard. Pharmacists reasonably want guidance as to when they may be “crossing the line.” Most of us want to do the right thing. It is difficult to innumerate each and every instance where a prescription is or is not being provided for a legitimate medical purpose. A prescription for two hundred tablets of Oxycontin may be completely appropriate for a given patient. A prescription for sixty tablets of Vicodin may be entirely inappropriate in a different situation. The law employs a flexible standard to try to cover both such situations.

The pharmacist's responsibility to verify a suspicious prescription can be met by contacting the prescriber. This is often easier said than done. Physicians are busy, can be difficult to locate (particularly hospital residents), and often may not regard pharmacist verifications as high priority tasks. Drug diverters come in all shapes and sizes. A pharmacist can't necessarily tell from “looks” alone whether a person is a legitimate patient or a drug addict. Experienced pharmacists may develop subjective feelings that something about a patient just does not seem quite right. At the same time, a history of close interaction with a patient over several months can confirm that a prescription is legitimate despite initial concerns.

It is increasingly common for physicians to require patients to sign a “Pain Treatment Agreement” as a condition of their receiving therapy for chronic pain, particularly when prescribing opioid analgesic medications. Such agreements are often provided as take-it-or-leave-it agreements and are not generally negotiated “contracts.” Written agreements have the potential to improve communication between physicians and patients, and enhance trust between physicians and patients, when they are used as tools to facilitate treatment. The agreements may also lead to a climate of distrust and suspicion. Where such agreements are involved, the pharmacist should be informed, though often the pharmacist is not informed. After all, the pharmacist is the one who is dispensing the medication. Many pharmacists would like to know when the prescriber would like to be contacted by the pharmacist – and when the prescriber believes it is “too early” to refill a prescription.

## Legal Literature

There are a number of sources of legal literature regarding this legal standard, such as federal and state court decisions and the Drug Enforcement Administration (DEA). Many sources discuss the phrase “legitimate medical purpose” and focus primarily on physician prescribing. As already discussed, pharmacists also need to understand this phrase and legal standard because of their corresponding legal duties.

On September 6, 2006, the DEA issued a Notice regarding Dispensing Controlled Substances for the Treatment of Pain. The notice discussed a number of instances where prescribers clearly issued prescriptions that were not for a “legitimate medical purpose.” For example, one prescriber gave a patient seven to ten prescriptions of OxyContin per visit on a weekly basis. The prescriptions were written in the patient's name as well as the names of the patient's family. Each visit, the patient paid a \$65 fee for the office visit plus an additional \$100 for the fraudulent prescriptions. The prescriber also asked the patient for sexual favors during office visits. The patient declined, but, as a substitute, paid another woman \$100 to perform a sexual act. The office assistant also provided the patient with blank prescriptions, in return for which the office assistant demanded from the patient \$40 and OxyContin tablets.

The DEA noted that the following types of behaviors result in sanctions:

- issuing prescriptions for controlled substances without a bona fide physician-patient relationship;
- issuing prescriptions in exchange for sex;
- issuing several prescriptions at once for a highly potent combination of controlled substances;
- charging fees commensurate with drug dealing rather than providing medical services;
- issuing prescriptions using fraudulent names; and
- self-abuse of controlled substances by practitioners.

The pharmacist will often not know if the prescriber is engaging in these acts. However, the pharmacist could also face sanctions for improperly dispensing controlled substances, rather than issuing prescriptions, for these same reasons.

The DEA notice also provided some sobering conclusions regarding the “legitimate medical purpose” standard, including:

1. Federal courts have long recognized that it is not possible to expand on the phrase “legitimate medical purpose in the usual course of professional practice” in a way that will provide definitive guidelines.
2. There are no specific guidelines concerning what is required to support a conclusion that an accused acted outside the usual course of professional practice. Rather, the courts must engage in a case-by-case analysis of evidence to determine whether a reasonable inference of guilt may be drawn from specific facts. See United States v. August, 984 F.2d 705, 713 (6th Cir. 1992).
3. It is a longstanding legal principle that the government can investigate merely on suspicion that the law is being violated, or even just because it wants assurance that it is

not. All law enforcement agencies - federal and state - have long been governed by this same principle. See United States v. Morton Salt Co., 338 U.S. 632, 642-643 (1950).

There have been reports of an increase in prescription drug abuse. There are a variety of factors that may be contributing to the increase in prescription drug abuse. The Director of The National Institute on Drug Abuse (NIDA) recently testified before Congress that the recent increase in the extent of prescription drug abuse is likely the result of a combination of factors, such as:

- increases in the number of prescriptions;
- increases in drug availability;
- aggressive marketing by the pharmaceutical industry;
- the proliferation of illegal Internet pharmacies that dispense these medications without proper prescriptions and surveillance; and
- a greater social acceptability for medicating a growing number of conditions.

The following recurring patterns have been identified as indicative of diversion and abuse by one court (See United States v. Rosen, 582 F.2d 1032 (5th Cir. 1978));

- Inordinately large quantities of controlled substances were prescribed.
- Large numbers of prescriptions were issued.
- No physical examination was given.
- The physician warned the patient to fill prescriptions at different drug stores.
- The physician issued prescriptions knowing that the patient was delivering the drugs to others.
- The physician prescribed controlled drugs at intervals inconsistent with legitimate medical treatment.
- The physician involved used street slang rather than medical terminology for the drugs prescribed.
- There was no logical relationship between the drugs prescribed and treatment of the condition allegedly existing.
- The physician wrote more than one prescription on occasions in order to spread them out.

Again, while these patterns are directed to prescribing, a similar list might be construed for dispensing. In other words, substitute the word “pharmacist” in place of the word “physician” and substitute the word “dispensed” in place of the word “prescribed.”

### **Opinion of Counsel**

One thing that practitioners can consider, to help reduce the prospects of criminal prosecution or civil liability, is to obtain an opinion from a lawyer. Remember that criminal acts require a criminal mind. A written opinion can be used to show a pharmacist was not “knowingly” engaged in “acts in deliberate or reckless disregard of the truth or falsity of the information” available to the pharmacist. No lawyer can or should guarantee a pharmacist that the pharmacist is completely immune from prosecution if the pharmacist follows the lawyer’s advice. A letter from a lawyer is not a silver bullet or a license to break the law. It can show the pharmacist was legitimately trying to do the right thing.

## Cases

Discussions of abstract principles can be useful for understanding the law. Examination of actual cases can also be helpful. The phrase “legitimate medical purpose” appears in only a few indexed cases in Ohio. The discussion of cases here in no way should be interpreted as an unfair criticism of any administrative agency or law enforcement agency. History teaches both lessons of actions to be followed and actions to avoid.

A well known pharmacy law professor and speaker, Dr. Jesse Vivian, discusses the subject of the legitimate medical purpose in the context of exempt narcotics. Ohio v. Hutton, Slip Op No L-00-1285 (February 22, 2002), 2002 Ohio App Lexis 753, Vivian J.C. Prosecution or Persecution? US Pharmacist. 2002; 27(4):57-59. The case involves a long and somewhat complicated history, including two trips to the Court of Appeals. Basically, a pharmacist in Toledo was indicted for drug trafficking after an examination of four years of his exempt narcotic records. The pharmacist sold codeine-based products in amounts considered excessive. The pharmacist was initially convicted and fined \$52,500.00, then eventually cleared. According to Dr. Vivian, the difference in the two outcomes was based in large part on the “legitimate medical need” for the exempt narcotics.

Another, somewhat older decision involved a physician initially convicted of improperly prescribing Seconal for insomnia. U.S. v. Carroll, 518 F.2d 187 (C.A.6 (Ohio), 1975). Dr. Carroll was charged with prescribing without a legitimate medical purpose. Ultimately, the Court of Appeals ruled that Dr. Carroll had been an industrious, innocent, law-abiding man with no previous disposition or intention to traffic in drugs - before government agents entrapped him. A full discussion of the legal doctrine of entrapment is beyond the scope of this lesson. In short, the Court found that Dr. Carroll was entrapped to violate the law when “officers implanted in the mind of [Dr. Carroll] the disposition to commit the alleged offense for the purpose of prosecuting him for the commission of a crime and, by repeated, persistent and incessant solicitation, so induced him and succeeded in accomplishing their purpose.”

Another case involved a physician being investigated for prescribing anabolic steroids for body building – a non-legitimate medical purpose. State v. Spencer, 126 Ohio App.3d 335, 710 N.E.2d 352 (Ohio App. 8 Dist., 1998). The physician refused to turn over subpoenaed records relating to his prescribing of the anabolic steroids. The appeal was directed to the physician’s duties to produce the records being sought. The physician was ultimately found to be in contempt for not producing the records and presumably ultimately did produce the records. While most dispensing records are now transmitted periodically to the Board of Pharmacy, the Board still has subpoena power if needed. If you receive a subpoena, you may contact your lawyer for more specific direction.

Another case discussed the legitimate medical purpose of sales of large amounts of exempted cough syrup with codeine. Vogelsong v. Ohio State Bd. of Pharmacy, 704 N.E.2d 28, 123 Ohio App.3d 260 (Ohio App. 4 Dist., 1997). At the Board hearing, at least one patient said the pharmacist never asked whether the patient had a cough and did

not tell the patient the cough syrup was potentially addictive. The Board's sanction of Pharmacist Vogelsong was ultimately upheld on appeal. The log books indicated that five people obtained a total of over eight hundred bottles of cough syrup with codeine from March 1992 through September 1993.

Oxycontin is used to treat intractable pain on a prolonged basis. Physician William Nucklos prescribed Oxycontin for three patients, was believed to have done so without a legitimate medical purpose, and was so charged. State v. Nucklos, 869 N.E.2d 674, 171 Ohio App.3d 38, 2007 Ohio 1025 (Ohio App., 2007). He was convicted, and appealed. At trial, there was evidence introduced that undercover police officers had posed as patients and had also been prescribed drugs by Dr. Nucklos. The state also offered in evidence medical records concerning treatment of over 200 other patients. The Court of Appeals reversed the conviction because use of the records of over 200 other patients was considered improper, basically designed to make the Dr. "look bad" in court. Also, the trial court was found to have wrongly placed the burden of proof on the Dr. to prove he was not guilty, instead of on the government to show Dr. Nucklos committed a crime. A full discussion of all the legal issues is beyond the scope of this lesson.

One practice note from the Nucklos case is the mention of guidelines found in OAC 4731-21, Drug Treatment of Intractable Pain. While a full discussion of OAC 4731-21 is beyond the scope of this lesson, we should be reminded that utilizing any prescription drug for the treatment of intractable pain on a protracted basis (or when managing intractable pain with prescription drugs in amounts or combinations that may not be appropriate when treating other medical conditions) requires an initial evaluation of the patient be conducted and documented in the patient's record and includes at least:

- a relevant history, including complete medical, pain, alcohol and substance abuse histories;
- an assessment of the impact of pain on the patient's physical and psychological functions;
- a review of previous diagnostic studies and previously utilized therapies; an assessment of coexisting illnesses, diseases or conditions; and an appropriate physical examination;
- a medical diagnosis established and documented in the patient's medical record that indicates the presence of intractable pain and the signs, symptoms, and causes and, if determinable, the nature of the underlying disease and pain mechanism; and
- an individualized treatment plan formulated and documented in the patient's medical record.

Courts view some cases involving legitimate medical purpose as very black and white. State v. Gotsis, 13 Ohio App.3d 282, 469 N.E.2d 548 (Ohio App. 9 Dist., 1984). In reviewing the facts of Dr. Gotsis, the record revealed that on at least nine occasions, undercover agents requested prescriptions for controlled substances - indicating to Dr. Gotsis that they had no medical problems and wanted the drugs for resale and/or for their own personal use to "get high." In each case, Gotsis did not elicit a chief complaint; did, at best, a cursory physical examination; and failed to take any patient history. Any

physician, indeed even a lay person, would know that issuing a prescription under these circumstances is “pushing drugs” and not practicing medicine.

While it perhaps does not need to be said, if a pharmacist hears a patient say the medications being dispensed are for resale and/or for their own personal use to “get high,” the pharmacist should refuse to dispense those medications. Granted, most drug abusers are rarely so forthcoming about plans to “get high.” As in the case of Dr. Gotsis, you might be speaking with an undercover law enforcement agent. He was.

A practitioner’s inability or unwillingness to say “no” and difficult life circumstances ultimately have little, if any, weight in court. U.S. v. Haj-Hamed, 549 F.3d 1020 (6th Cir., 2008). Dr. Haj-Hamed was sentenced to twenty-seven months of imprisonment after he was found to have routinely spoken to patients for a minute or so without conducting any meaningful physical examination then prescribed frequently-abused controlled substances to the patients in exchange for cash payments. A federal grand jury indicted Dr. Haj-Hamed on twenty-two counts of distributing prescription drugs without a legitimate medical purpose. There is little reason to think that a pharmacist that knew all these facts, and filled the prescriptions any, would have fared any better.

Dr. Haj-Hamed admitted to his difficulty in refusing persons who ask for his help. He also had eight children with his wife, principally a homemaker, having attained only the equivalent of a seventh-grade education, and did not have strong English-language skills. Three of the children were step-children from his wife's previous marriage to Dr. Haj-Hamed's brother, who had died years before in an automobile accident. While the case was no doubt difficult for the physician and the family, the Court of Appeals did not change the sentence.

No doubt, there are countless clear cases of physicians and pharmacists improperly prescribing and dispensing controlled substances.

### **Conclusion**

This topic is admittedly less cut and dry than many others. The reason is that it is sometimes difficult to determine when a patient is genuinely in pain and using medication for a legitimate medical purpose. Sometimes, it’s not so difficult. Relying on your professional instincts and training will go along way in helping you decide when to dispense and when to not dispense.

Questions – choose the one most correct answer. A passing score is seventy percent.

1. The pharmacist must determine the legitimate medical need for which of the following before dispensing them to a patient.
  - a. exempt narcotics
  - b. controlled substances
  - c. antibiotics
  - d. all of the above
2. A pharmacist may avoid all legal responsibility in dispensing controlled substances by claiming “it’s hard to say no.”
  - a. true
  - b. false
3. A 23-year-old patient presents a written prescription from a physician’s office located in Florida. The prescription is written by a pediatrician for two hundred tablets of methadone 10mg, to be taken every two hours. The patient offers to pay cash when he drops off the prescription. In deciding whether to dispense the medication for a legitimate medical purpose, the pharmacist should consider which of the following factors:
  - a. the age of the patient
  - b. offer to pay cash
  - c. location of the physician’s office
  - d. amount of tablets
  - e. all of the above
4. A patient can have a prescription for a legitimate medical purpose for large amounts of controlled substances when a physician has never performed a physical examination for that patient.
  - a. true
  - b. false
5. To be convicted of a crime pertaining to dispensing medication without a legitimate medical purpose, it must be shown that the pharmacist acted with which of the following state of mind:
  - a. Negligently
  - b. Knowingly
  - c. Recklessly
  - d. intentionally
6. According to the VIGIL approach for dispensing controlled substances for a legitimate medical purpose, government issued ID should be viewed for a patient and family members picking up prescriptions.
  - a. true
  - b. false
7. If a pharmacist hears a patient say the medications being dispensed are for resale and/or for their own personal use to “get high,” the pharmacist should refuse to dispense those medications.
  - a. true
  - b. false

8. It is possible to explain the phrase “legitimate medical purpose” in a way that will provide definitive guidelines about when to refuse to fill prescriptions.
  - a. true
  - b. false
9. The recent increase in the extent of prescription drug abuse is likely the result of:
  - a. increases in the number of prescriptions
  - b. increases in drug availability
  - c. aggressive marketing by the pharmaceutical industry
  - d. a greater social acceptability for medicating a growing number of conditions
  - e. all of the above
10. Examples of activities which likely indicate diversion and abuse include:
  - a. lack of logical relationship between the drugs prescribed and treatment of the condition allegedly existing
  - b. filling prescriptions at a large number of different pharmacies
  - c. prescribing controlled substances for children
  - d. receiving treatment from a specialist, such as a rheumatologist
  - e. a and b



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Approved for one contact hour of Ohio Jurisprudence by the Ohio State Board of Pharmacy

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Answer Sheet – circle the one correct best answer. Credit will be granted with seven correct answers.

Question	Answer	Question	Answer
1	A B C D	6	True False
2	True False	7	True False
3	A B C D E	8	True False
4	True False	9	A B C D E
5	A B C D	10	A B C D E



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- How would you rate this educational program overall?  
 excellent | very good | Good | Fair | Poor
- How well did this program achieve its educational objectives?  
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- How useful and relevant will this lesson be in your practice?  
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 30 minutes | 45 minutes | 60 minutes | 90 minutes | Over 90 minutes